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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,964	07/27/2005	Richard Lehman	P26,128 A USA	8571

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EXAMINER	
WINKLER, MELISSA A	
ART UNIT	**PAPER NUMBER**
1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,964	LEHMAN ET AL.	
	Examiner	Art Unit	
	MELISSA WINKLER	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *13-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted:

Group I, Claim(s) 1-12, drawn to a tissue compatible polymer composite;

Group II, Claim(s) 13-20, drawn to a tissue compatible polymer structure;

Group III, Claim(s) 21, drawn to an implantable medical device or tissue scaffold made from a tissue compatible polymer composite;

Group IV, Claim(s) 22, drawn to a method for forming a tissue compatible polymer structure; and

Group V, Claim(s) 23, drawn to a method for ensuring biocompatibility with a tissue compatible polymer composite.

The inventions listed as **Groups I - V** do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common

technical feature in all groups is a polymer which is biocompatible. This element cannot be seen as a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. U.S. Patent 4,173,689 (Abstract) teaches that polymer tissue analogues are made from biocompatible polymers as claimed in claims 1, 13, 21, 22, and 23.

During a telephone conversation between Peter Butch and Examiner Timothy Kennedy on October 29, 2008, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or

otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 5 and 7 – 12 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0143403 to Vaidyanathan et al.

Regarding Claims 1 – 5 and 7 - 12. Vaidyanathan et al. teach a biomedical implant with a porosity effective for promoting natural bone growth around the exterior of the implant, i.e. the implant is tissue-compatible. (Paragraph 31). The implant structure may comprise a polymer such as polymethylmethacrylate (PMMA) (Paragraph 36).

A growth-enhancing composition may be applied to the implant structure as a water-based suspension that forms a coating on the surface and within the pore space of the structure (Paragraph 44). The growth-enhancing composition includes polymers, such as polylactic acid (PLA) and polyglycolic acid (PGA), and a calcium source, such as tricalcium phosphate (Paragraph 41). The growth-enhancing composition begins to erode after implantation to stimulate bone growth. As bone grows at the site, it

eventually replaces the growth-enhancing composition within the pores and on the surface of the implant structure. The implant structure degrades at a slower rate than the growth-enhancing composition but it, too, is eventually replaced by new bone and tissue growth (Paragraph 40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0143403 to Vaidyanathan et al., as applied to Claims 1 and 3 above.

Regarding Claim 6. Vaidyanathan et al. teach the polymer composite of Claim 3 comprising an implant structure which may comprise a polymer such as polymethylmethacrylate (PMMA) and a growth-enhancing composition that may be applied to the structure as a water-based suspension and that includes polymers, such as polylactic acid (PLA) and polyglycolic acid (PGA) (Paragraphs 36, 41, and 44).

Vaidyanathan et al. are silent regarding the ratio of the polymer in the implant structure, for example PMMA, to that in the growth-enhancing composition, for example PLA and/or PGA. However, the experimental modification of this prior art in order to ascertain optimum operating conditions fails to render applicants' claims patentable in the absence of unexpected results. *In re Aller*, 220 F.2d 454, 105, 105 USPQ 233 (CCPA 1955) (MPEP 2144.05) At the time of the invention, it would have been obvious to a person of ordinary skill in the art to optimize the amount of growth enhancing composition used – and, therefore, the amount of PLA and/or PGA used – relative to the implant structure which may be comprised of PMMA so that bone growth in the host could be most effectively stimulated. A prima facie case of obviousness may be rebutted, however, where the results of the optimizing variable, which is known to be result-effective, are unexpectedly good. *In re Boesch and Slaney*, 617 F.2d 272, 205, 205 USPQ 215 (CCPA 1980) (MPEP 2144.05)

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA WINKLER whose telephone number is

(571)270-3305. The examiner can normally be reached on Monday - Friday 7:30AM - 5PM E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/ MW
Supervisory Patent Examiner, Art Unit 1796 December 11, 2008